

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-75(cancelled)

76 (Withdrawn/Currently Amended). A method for modulating the immune response of a subject, the method ~~comprises comprising~~ administering to said subject a ~~sphingoid-polyalkylamine conjugate together with a biologically active molecule, the biologically active molecule being effective to modulate said immune response~~vaccine according to claim 108.

77 (Withdrawn/Currently Amended). The method of Claim 76, wherein said sphingoid-polyalkylamine conjugate comprises a sphingoid backbone carrying, via a carbamoyl bond,at least one polyalkylamine chain.

78 (Withdrawn). The method of Claim 76, wherein said modulation includes stimulation or enhancement of the immune response.

79 (Withdrawn/Currently Amended). The method of ~~any~~
~~one of Claims~~claim 76, wherein said biologically active molecule
is associated with said sphingoid-polyalkylamine conjugate.

80 (Withdrawn). The method of Claim 76, wherein said
biologically active molecule has, at a physiological pH, a net
negative dipole moment, a net negative charge or contains at
least one region having a net negative charge.

81 (Withdrawn). The method of Claim 76, wherein said
biologically active molecule is an immunomodulator selected from
the group consisting of a nucleic acid molecule, an amino acid
molecule ~~or~~and a low molecular weight compound.

82 (Withdrawn/Currently Amended). The method Claim
76, wherein said biologically active molecule is ~~selected from~~
an antigenic protein, antigenic peptide, antigenic polypeptide,
or a carbohydrate.

83 (Withdrawn/Currently Amended). The method Claim
76, wherein said nucleic acid molecule is an
~~oligodeoxynucleotides~~oligodeoxynucleotide (ODN).

84 (Withdrawn). The method of Claim 76, further comprising administering to said subject an immunostimulating agent.

85 (Withdrawn/Currently Amended). The method of Claim 84, wherein said immunostimulating agent is administered concomitant with, or within a time interval before or after administration of said sphingoid-polyalkylamine conjugate.

86 (Withdrawn). The method of Claim 76, wherein said sphingoid-polyalkylamine conjugate forms a lipid assembly.

87 (Withdrawn/Currently Amended). The method of Claim 86, wherein said lipid assembly comprises vesicles or micelles or a combination of same.

88 (Withdrawn). The method of Claim 87, wherein said biologically active molecule is associated with said lipid assembly.

89 (Withdrawn/Currently Amended). The method of Claim 76, wherein the sphingoid is selected from the group consisting of ceramide, dihydroceramide, phytoceramide,

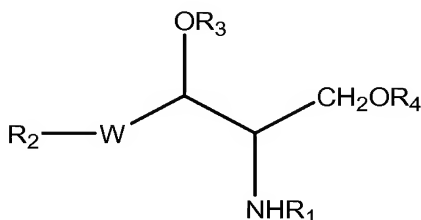
dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine,
and dihydrophytoceramine.

90 (Withdrawn). The method of Claim 89, wherein said sphingoid is ceramide.

91 (Withdrawn/Currently Amended). The method of Claim 90, wherein said polyalkylamine is ~~selected from spermine, spermidine, a polyamine analog or a combination of same thereof.~~

92 (Withdrawn). The method of Claim 76, wherein said sphingoid-polyalkylamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS).

93 (Withdrawn/Currently Amended). The method of Claim 76, wherein said sphingoid-polyalkylamine conjugate has the following formula (I):



wherein

R₁ represents a hydrogen, a branched or linear alkyl, aryl, alkylamine, or a group -C(O)R₅;

R₂ and **R₅** represent, independently, a branched or linear C₁₀-C₂₄ alkyl, alkenyl or polyenyl ~~group~~group;

R₃ and **R₄** are, independently, a group -C(O)-NR₆R₇, in which **R₆** and **R₇** being the same or different for **R₃** and **R₄**, and represent, independently, a hydrogen, or a saturated or unsaturated branched or linear polyalkylamine, wherein one or more amine units in said polyalkylamine may be a quaternary ammonium; or **R₃** is a hydrogen; or **R₃** and **R₄** form, together with the oxygen atoms to which they are bound, a heterocyclic ring comprising -C(O)-NR₉-[R₈-NR₉]_m-C(O)-, in which **R₈** represents a saturated or unsaturated C₁-C₄ alkyl and **R₉** represents a hydrogen or a polyalkylamine of the formula -[R₈-NR₉]_n-, wherein said **R₉** or each alkylamine unit -R₈NR₉ may be the same or different in said polyalkylamine; and **n** and **m**, represent, independently, an integer from 1 to 10; and

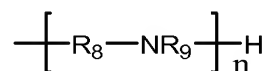
W represents a ~~group selected from~~ -CH=CH-, -CH₂-CH(OH)- or -CH₂-CH₂- group.

94 (Withdrawn). The method of Claim 93, wherein **R₁** represents a -C(O)R₅ group, **R₅** being as defined.

95 (Withdrawn/Currently Amended). The method of Claim 93, wherein said **R₂** and **R₅** represent, independently, a linear or branched C₁₂-C₁₈ alkyl or alkenyl ~~group~~group.

96 (Withdrawn). The method of Claim 93, wherein W represents -CH=CH-.

97 (Withdrawn). The method of Claim 93, wherein R₁ represents a -C(O)R₅ group; R₅ represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; W represents -CH=CH-; R₂ represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; R₃ and R₄ represent, independently, a group -C(O)-NR₆R₇, and R₃ may also represent a hydrogen, wherein R₆ and R₇ represent, independently, a hydrogen or a polyalkylamine having the general formula (II):



wherein

R₈ represent a C₁-C₄ alkyl;

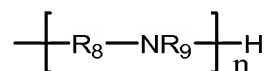
R₉ represents a hydrogen or a polyalkylamine branch of formula (II), said R₈ and R₉ may be the same or different for each alkylamine unit, -R₈NR₉-, in the polyalkylamine of formula (II); and

n represents an integer from 3 to 6.

98 (Withdrawn). The method of Claim 93, wherein R₃ is a hydrogen atom.

99 (Withdrawn). The method of Claim 93, wherein both R_3 and R_4 represent the same or a different polyalkylamine.

100 (Withdrawn/Currently Amended). The method of Claim 93, wherein R_1 represents a $-C(O)R_5$ group; R_5 represents a C_{12} - C_{18} linear or branched alkyl or alkenyl; W represents $-CH=CH-$; R_2 represents a C_{12} - C_{18} linear or branched alkyl or alkenyl; R_3 and R_4 represent, independently, a group $-C(O)-NR_6R_7$, wherein R_6 and R_7 represent, independently, an alkylamine or a polyalkylamine having the general formula (II):



wherein

R_8 ~~represent~~ represents a C_1 - C_4 alkyl;

R_9 represents a hydrogen or a polyalkylamine branch of formula (II), said R_8 and R_9 may be the same or different for each alkylamine unit, $-R_8NR_9-$, in the polyalkylamine of formula (II); and

n represents an integer from 3 to 6.

101 (Withdrawn/Currently Amended). The method of Claim 93, wherein R_1 represents a $-C(O)R_5$ group; R_5 represents a C_{12} - C_{18} linear or branched alkyl or alkenyl; W represents $-CH=CH-$; R_2 represents a C_{12} - C_{18} linear or branched alkyl or alkenyl; R_3 and R_4 form together with the oxygen atoms to which they are

bonded a heterocyclic ring comprising $-C(O)-[NH-R_8]_n-NH-C(O)-$, wherein R_8 represents a C_1-C_4 alkyl, and wherein for each alkylamine unit having the formula $-NH-R_8-$, said R_8 may be the same or different; and n represents an integer from 3 to 6.

102 (Withdrawn). The method of Claim 93, wherein said R_8 is a C_3-C_4 alkyl.

103 (Withdrawn). The method of Claim 76, wherein said biologically active material is derived from influenza virus or an analog of a molecule derived from influenza virus.

104 (Withdrawn). The method of Claim 103, wherein said biologically active material is a combination of hemagglutinin and neuraminidase (HN).

105 (Withdrawn). The method of Claim 76, comprising intranasal or intramuscular administration of said conjugate.

106 (Withdrawn). The method of Claim 92, comprising intranasal or intramuscular administration of said N-palmitoyl D-erythro sphingosyl carbamoyl-spermine together with said biologically active molecule.

107 (Withdrawn/Currently Amended). A method for stimulating or enhancing the immune response of a subject to influenza virus, the method ~~comprises~~ comprising providing said subject with N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS) together with an influenza antigen.

108 (Previously Presented). A vaccine comprising sphingoid-polyalkylamine conjugate and an amount of a biologically active molecule, the amount of said biologically active molecule being effective to modulate the immune response of a subject.

109 (Previously Presented). The vaccine of Claim 108, wherein said biologically active molecule is effective to stimulate or enhance the immune response of said subject.

110 (Previously Presented). The vaccine of Claim 109, further comprising an immunostimulating agent.

111 (Currently Amended). The vaccine of claim 108, wherein said sphingoid-polyalkylamine conjugate comprises a sphingoid backbone carrying, via a carbamoyl bond, at least ~~at least~~ one polyalkylamine chain.

112 (Currently Amended). The vaccine of Claim 111, wherein said sphingoid backbone is selected from the group consisting of ceramide, dihydroceramide, phytoceramide, dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine, and dihydrophytoceramine.

113 (Previously Presented). The vaccine of Claim 112, wherein said sphingoid is ceramide.

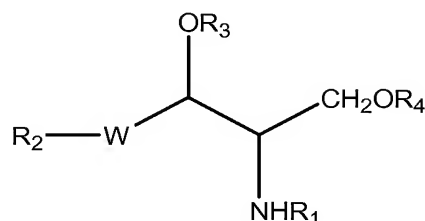
114 (Currently Amended). The vaccine of Claim 108, wherein said polyalkylamine chain is ~~selected from~~ spermine, spermidine or a polyalkylamine analog of spermine or spermidine.

115 (Previously Presented). The vaccine of Claim 108, wherein said sphingoid-polyalkylamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS).

116 (Previously Presented). The vaccine of Claim 115, wherein said biologically active molecule is a molecule derived from influenza virus or is an analog of a molecule derived from influenza virus.

117 (Canceled).

118 (Currently Amended). The vaccine of Claim 33, wherein said sphingoid-polyalkylamine conjugate has the following formula (I):



wherein

R₁ represents a hydrogen, a branched or linear alkyl, aryl, alkylamine, or a group -C(O)**R**₅;

R₂ and **R**₅ represent, independently, a branched or linear C₁₀-C₂₄ alkyl, alkenyl or polyenyl ~~group~~group;

R₃ and **R**₄ are, independently, a group -C(O)-NR₆**R**₇, in which **R**₆ and **R**₇ being the same or different for **R**₃ and **R**₄, ~~and~~ represent, independently, a hydrogen, or a saturated or unsaturated branched or linear polyalkylamine, wherein one or more amine units in said polyalkylamine may be a quaternary ammonium; or **R**₃ is a hydrogen; or **R**₃ and **R**₄ form, together with the oxygen atoms to which they are bound, a heterocyclic ring comprising -C(O)-NR₉-[**R**₈-NR₉]_m-C(O)-, in which **R**₈ represents a saturated or unsaturated C₁-C₄ alkyl and **R**₉ represents a hydrogen or a polyalkylamine of the formula -[**R**₈-NR₉]_n-, wherein said **R**₉ or each alkylamine unit -**R**₈NR₉ may be the same or different in

said polyalkylamine; and n and m , represent, independently, an integer from 1 to 10; and

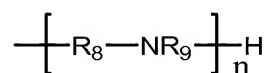
W represents a ~~group selected from~~ $-\text{CH}=\text{CH}-$, $-\text{CH}_2-$ $\text{CH}(\text{OH})-$ or $-\text{CH}_2-\text{CH}_2-$ group.

119 (Previously Presented). The vaccine of Claim 118, wherein R_1 represents a $-\text{C}(\text{O})\text{R}_5$ group, R_5 being as defined.

120 (Currently Amended). The vaccine of Claim 118, wherein said R_2 and R_5 represent, independently, a linear or branched $\text{C}_{12}-\text{C}_{18}$ alkyl or alkenyl ~~groups~~ group.

121 (Previously Presented). The vaccine of Claim 118, wherein W represents $-\text{CH}=\text{CH}-$.

122 (Previously Presented). The vaccine of Claim 118, wherein R_1 represents a $-\text{C}(\text{O})\text{R}_5$ group; R_5 represents a $\text{C}_{12}-\text{C}_{18}$ linear or branched alkyl or alkenyl; W represents $-\text{CH}=\text{CH}-$; R_2 represents a $\text{C}_{12}-\text{C}_{18}$ linear or branched alkyl or alkenyl; R_3 and R_4 represent, independently, a group $-\text{C}(\text{O})-\text{NR}_6\text{R}_7$, and R_3 may also represent a hydrogen, wherein R_6 and R_7 represent, independently, a hydrogen or a polyalkylamine having the general formula (II):



wherein

R₈ represent a C₁-C₄ alkyl;

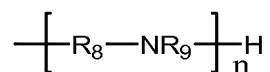
R₉ represents a hydrogen or a polyalkylamine branch of formula (II), said R₈ and R₉ may be the same or different for each alkylamine unit, -R₈NR₉-, in the polyalkylamine of formula (II); and

n represents an integer from 3 to 6.

123 (Previously Presented). The vaccine of Claim 118, wherein R₃ is a hydrogen atom.

124 (Previously Presented). The vaccine of Claim 118, wherein both R₃ and R₄ represent the same or a different polyalkylamine.

125 (Currently Amended). The vaccine of Claim 118, wherein R₁ represents a -C(O)R₅ group; R₅ represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; W represents -CH=CH-; R₂ represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; R₃ and R₄ represent, independently, a group -C(O)-NR₆R₇, wherein R₆ and R₇ represent, independently, an alkylamine or a polyalkylamine having the general formula (II):



wherein

R₈ ~~represent~~ represents a C₁-C₄ alkyl;

R₉ represents a hydrogen or a polyalkylamine branch of formula (II), said **R₈** and **R₉** may be the same or different for each alkylamine unit, -**R₈****NR₉**-, in the polyalkylamine of formula (II); and

n represents an integer from 3 to 6.

126 (Currently Amended). The vaccine of Claim 118, wherein **R₁** represents a -C(O)**R₅** group; **R₅** represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; **W** represents -CH=CH-; **R₂** represents a C₁₂-C₁₈ linear or branched alkyl or alkenyl; **R₃** and **R₄** form together with the oxygen atoms to which they are bonded a heterocyclic ring comprising -C(O)-[NH-**R₈**]_{**n**}-NH-C(O)-, wherein **R₈** represents a C₁-C₄ alkyl, and wherein for each alkylamine unit having the formula -NH-**R₈**-, said **R₈** may be the same or different; and **n** represents an integer from 3 to 6.

127 (Previously Presented). The vaccine of Claim 118, wherein said **R₈** is a C₃-C₄ alkyl.

128-134 (Canceled).